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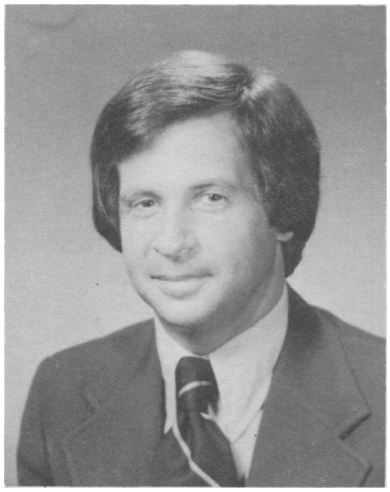

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Physicians' Office Laboratories: Current and Future Status

With the development of sophisticated computerized technology and the advent of new biochemical processes, the modern clinical laboratory has undergone a revolutionary change. Coupled with changes in reimbursement, many laboratory studies previously performed by independent laboratories are now being accomplished within physician offices. Because of the increasing availability of this equipment and the relative ease of performing the studies, more and more physicians are contemplating purchasing equipment to perform these studies in-house. The laboratory industry itself, although directly responsible for scientific advancement in these areas, feels threatened by the possible loss of revenue such a move may produce. Furthermore, they are concerned that the quality of the studies being performed will be less than optimal. They also feel that physician office laboratory facilities do not have to undergo the same regulatory scrutiny that independent laboratories must face, and therefore these laboratories have an unfair competitive edge in the marketplace. In addition, there is under Medicare rules, a distinct advantage to physicians, from a financial point of view, to have these studies performed in office rather than at an independent laboratory. There is thus a great push at the federal level to offer legislation that will regulate and make the physician office laboratory comparable to that of the independent laboratory. It is hoped that in so doing the glamour of establishing an independent laboratory will recede once it becomes apparent that "costs of doing business" will make any profit motive for establishing such a facility unrewarding.

In defense of physician office laboratories, there are several advantages to leaving them in place and not legislate them out of existence. Firstly, rapid studies can be obtained in no other fashion when patients are acutely ill in an office setting. For instance, immediate blood sugar determinations, white blood counts, serum potassium or sodium measurements, as well as blood gas determinations and others, can have immediate therapeutic ramificaitons, and thus need to be available rapidly. The ability for physician offices to offer these services to their patients is really not a luxury, but a necessity. As such, there has to be some ability for physicians to obtain these services, and at the moment there are no alternatives to having an in-house laboratory. Eliminating such a facility

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could produce serious patient care problems.

There is no question that the quality of the studies one obtains should be the same whether it is in an independent laboratory or in a physician facility. In fact, there are several laboratories that have been developed which offer "better quality" procedures, indicating that even within an independent laboratory environment there are some firms which are providing better quality studies than others, especially in specialty areas. This would indicate that the quality issue should not just be directed to physician office laboratories, but needs to be addressed to the general laboratory community as well. There are stringent Medicare rules and state licensing rules for independent laboratories. These have been waived for physician office laboratories when those laboratories are performing studies only on their own patients. Part of the rationale for this has been that physician office laboratories are under the direction of the physician who is caring for the patient and he will be immediately aware of deficiencies or excesses that occur in the laboratory when results return, since he is intimately involved in the patient's care and knows about his or her medical problems. In an independent setting, such is not the case and there are no good controls along those lines, necessitating the need for tight supervision of the laboratory by other means. I personally am of the opinion that tighter regulation of physician office laboratories ultimately will be beneficial to the patient, as well as the physician who is running the laboratory, and am in favor of quality controls. The latter are available through multiple sources including the American College of Pathology and the American Society of Internal Medicine. The cost for these control quality assurance programs is not excessive, and appears affordable to just about all physician office laboratories.

The issue of differential reimbursement for laboratory services performed in a physician's office compared to an independent laboratory is a difficult one to deal with, but obviously there are differences in cost when volume is taken into consideration. The lower volume of an individual physician office laboratoy results in higher costs, and therefore higher reimbursement seems appropriate. Nevertheless, close scrutiny of reimbursement patterns should be undertaken, and if there appears to be excess reimbursement, it should be trimmed, but again, the cost of performing the study in different environments needs to be taken into consideration when final decisions are rendered.

In summary, I believe physician offices should be permitted to have laboratory facilities, these facilities should be of high quality, and should be subject to "peer review" by a recognized national quality assurance service such as that offered by the American College of Pathologists or the American Society of Internal Medicine. Reimbursement for physician office laboratory studies should be based on cost considerations which should not necessarily mean that they should be equated with fees paid to independent commercial laboratories. Quality assurance is of utmost importance and should be directed not only to physician offices, but to the entire clinical laboratory industry. Within our present environment the above considerations should result in a better patient acceptance and physician reliance on in-house office results. □

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